2/26/2013

55195-4



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

ITW Dymon c/o for Colcide, Inc 805 E. Old 56 Highway Olathe, KS 66061

Attention: Melissa Schnake Regulatory Specialist

FEB 26 2013

Subject:

Coldcide 0.25% Disinfecting Wipes

EPA Reg. No. 55195-4

Application Dated January 15, 2013

This will acknowledge receipt of your notification submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

• Updating Storage and Disposal Language

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely.

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1 Antimicrobials Division (7510C)

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Please read instructions on reverse before completing form. United States Environmental Protection Age Washington, DC 20460				ncy	Form Appro	×	Registrat Amendm Other	ion	OPP Identifier Number	
		Applicatio	n for F	estici	de - Sect	tion	l			
1. Company/Product Number 55195-4				2. EPA Product Manager Swindell			3. Pr	oposed Classification		
4. Company/Product (Name) ColdCide 0.25% Disinfecting Wipes				PM#				None Restricted		
5. Name and Address of App ColCide, Inc. 11500 W. Hill Dr. Rockville, MD 20852	licant <i>(Include ZIP Co</i>	odej	÷	(b)(i), r to: EPA I	ny product i	is sin	nilar or identio	al in co	FIFRA Section 3(c)(3) imposition and labeling	
			Sect	ion -						
Amendment - Explain Resubmission in responsion - Explain I Explanation: Use addition This Notification is for addition also have deleted all Tube claims and language remains.	below. al page(s) if necessar ling Direction for U	y. (For section	to our lab	el in ord	Agency lett "Me Too" A Other - Expl	ter da Applic Isin b	elow. elow. te different si	zes and		
			Sect	ion - l	II					
1. Material This Product Will	Be Packaged in:									
Yes* No If "Yes" No. per			If "Yes					Specify)		
3. Location of Net Contents I	nformation ontainer	4. Size(s) Ret	tail Contair	ner		5. La	Ocation of Label On Label On Labeli		ons npanying product	
6. Manner in Which Label is Affixed to Product Lithog Paper Stenc			graph Other							
				ion - I	V					
1. Contact Point Complete	items directly below I	for identificatio	n of indivi	dual to b	e contacted,	if nec	cessary, to pro	cess this	s application.)	
Name Velissa Schnake Title Age			Title Agent				- 1	Telephone No. ປົກຕິບິປອ Area Code) 913-489-3111		
I certify that the stater I acknowledge that an both under applicable I	y knowingly false or r		all attach				୍ଧ curate and con mprisonment c	ងខែខេះ - ខ	6. Date Application Beceived	
2. Signature			3. Title Agent				-:	1		
2. Signature									((((((((((((((((((((



January 15, 2013

U.S. Environmental Protection Agency Document Processing Desk (NOTIF) Office of Pesticide Programs (7504 P) 1200 Pennsylvania Ave. NW Washington DC 20460

Dear Sir or Madam:

Enclosed please find all the documents and paperwork necessary for a Notification to the current registration of EPA #55195-4 Coldcide 0.25% Disinfecting Wipes.

I have included our Application and our Master label for your approval. See Certification Statement below.

Please let me know if there is any further information required. Also, I would like to be informed via email as my submission is routed through the process.

Regards

Melissa Schnake

Sr. Regulatory Specialist mschnake@dymon.com

Encl.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

MASTER LABEL COLDCIDE 0.25% WIPES All word(s), phrases, or symbols in {} and bolded are OPTIONAL

PAGE 1

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Light Floral Scent

ColdCide

0.25% DISINFECTING WIPES

A stable, low pH formulated disinfectant and deodorant for use in hospitals, medical offices, dental offices, veterinary facilities, janitorial, commercial and industrial facilities for use on hard surfaces.

Bactericidal Virucidal* Pseudomonicidal Fungicidal

Active Ingredients

Glutaraldehyde 0.27500% O-Phenylphenol 0.01375% P-Tertiary Amylphenol 0.00275% Inert Ingredients** 99.70850% TOTAL 100.00000%

**Does not include weight of dry wipe.

Net Contents: XX lbs xx oz (XXX grams)
Contains: XXX xx in X xx in {(xx cm X xx cm)}

{Wipe} {s} {Saturated with Disinfectant} {Disinfectant {Disinfecting} Wipes}

CAUTION

KEEP OUT OF REACH OF CHILDREN

See {side} {back} {rear} {attached} panel {label} for additional precautionary statements.

Kills Herpes simplex virus types 1 & 2, Methicillin-Resistant Staphylococcus Aureus (MRSA) & HIV-1 (AIDS virus)* on hard non-porous surfaces.

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)

{use one of the following, complete paragraphs omitted on single pack container}

PREPARATION OF DISPENSER: Open top of tub, remove and discard covering seal. From center of wipes roll, pull up a wipe corner, twist into a point and thread through the X hole in the underside of the lid cover. Pull wipe through about one (1) inch. Replace the lid cover on container, assuring a secure fit. Pull out first wipe and snap at a 90' angle. Remaining wipes feed automatically for next use. Always reseal hinged cap after each use to insure moisture retention.

DIRECTIONS FOR DISPENSING:

Remove lid from container. From center of towel roll, pull up a towel corner, twist into a point and thread through the X hole in the underside of the lid. Pull towel through about one inch. Replace lid on container, assuring a secure fit. Pull out first towel and snap off at 90° angle. Remaining towels feed automatically for next use. Always reseal hinged cap after each use to insure moisture retention.

DIRECTIONS FOR DISPENSING

Remove lid. Pull wipe up from the center of the roll and twist into a point. Push twisted wipe through center of notched opening in the underside of the lid. Replace lid, making sure lid fits securely. Pull out wipe at a 90 degree angle and tear off at perforation. Dispose of properly. Remaining wipes feed accommodate for next use. Always reseal hinged cap to insure against moisture loss and contamination.

DIRECTIONS FOR DISPENSING:

1. Lift tab at front of lid to open.

2. Pull up corner of center sheet and thread through dispenser slit in front. Pull out exposed wipe at a 45° angle and snap off. The next wipe is ready for dispensing.

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COLDCIDE 0.25% WIPES MASTER LABEL All word(s), phrases, or symbols in {} and bolded are OPTIONAL

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- Close lid to retain moisture.
- 4. Dispose of used wipe in trash receptacle. Do not flush.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

EPA Reg. No.

55195-4-{XXXXX}

EPA Est. No.

11694-KS-1

{Manufactured} {Sold} {Distributed} {in the U.S.A.} {by} {for}

(ITW Dymon) {805 E. Old 56 Highway} {Olathe, KS 66061}

{ColCide, Inc.} {11500 W. Hill Dr.} {Rockville, MD 20852}

{PRODUCT/MSDS DOCUMENT # xxxxx}

{DIRECTIONS} FOR USE:}}

It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling. Use one (product name) (wipe) (towel) to completely remove surface of all gross debris from surfaces to be treated. For use as a general disinfectant wipe on hard, non-porous inanimate surfaces {such as counter tops,} {exam tables,} {cages,} {toilets,} {basins,} {tubs,} {bed springs,} {frames,} {bedside {and office} furniture,} {chart racks and equipment,} {cabinets,} {door knobs,} {office machinery,} {sinks,} {mirrors,} {light fixtures and switches,} {supply,) (dressing,} {and trash} carts,} {telephones,} (waste cans and laundry hampers,} {wheel chairs,} (and walkers,} {urinals,} {plastic} {and other similar hard surfaces}. Use as many wipes as needed for the surface to remain wet for the entire 10 minute contact time.

DISINFECTION:

ColdCide - 0.25% Disinfecting Wipes kill Salmonella choleraesuis, Staphylococcus aureus, Methicillin-Resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa, Trichophyton mentagrophytes, and Human Coronavirus (HcoV) in 10 minutes at 20°C/68°F or higher. Herpes simplex virus 1& 2 and Influenza A2HK are inactivated in 30 seconds, and the listed viruses* within 2 minutes at 20°C/68°F or higher. Coxsackie virus B5a, Adenovirus-2, Poliovirus 1&2, Rotavirus SA-11, Rhinovirus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus. Kills Pandemic H1N1 influenza A virus (formerly called swine flu).

ColdCide-0.25% Disinfecting Wipes inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces in 30 seconds at room temperature (20-25°C). ژه د د ر د

DEODORIZING: Wipe hard, non-porous surfaces thoroughly to eliminate odors duff for spillage from {post-colostomy,} {post-ileostomy} {dressing} {s} and {bag change {s}, {and°other̂} spillຣົ ເນເດີເລ as urine or fecal matter; smoke or soot deposits , industrial plant processes, mildew and michigan sourtaces in musty closets. ,,,,,,

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MASTER LABEL

COLDCIDE 0.25% WIPES

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{Box border optional}

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals

CAUTION: MAY BE IRRITATING TO EYES. Do not get in eyes, on skin or on clothing. Wear rubber gloves when handling. Repeated dermal contact may result in dermal sensitization in some individuals. Avoid contamination of food. Avoid reuse of unwashed, disinfectant-soaked gloves. Avoid prolonged inhalation.

{Box border optional}

FIRST AID:

IF IN EYES: Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

WASH THOROUGHLY AFTER HANDLING WIPES.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Store in cool area inaccessible to children.

CONTAINER STORAGE/DISPOSAL: Wipes: Dispose of (wipe) (towel) in trash after use. Do not flush. Canister: Tightly close lid between uses to retain moisture. Nonrefillable container. Do not reuse or refill this (container) (canister). Offer empty (container) (canister) for recycling if available or discard in trash.

THE ACTIVITY OF COLDCIDE 0.25% DISINFECTING WIPES AGAINST THE HIV-1 (AIDS VIRUS):

ColdCide - 0.25% Disinfecting Wipes completely inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces when used at a contact time of 30 seconds at room temperature (20-25°C). Although efficacy at a 30-second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10 minute contact time for disinfection against all of the organisms claimed on the label. **ColdCide 0.25% Disinfecting Wipes** kill HIV-1 on pre-cleaned environmental surfaces/objects soiled with blood/body fluids, in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of ColdCide-0.25% Disinfecting Wipes.

Contact Time: While the HIV-1 virus is inactivated in 30 seconds, use the recommended contact time for disinfection of other organisms on this label.

Disposal of Infectious Materials: Materials that may contain blood or other body fluids, must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

{For an MSDS, call XXXXXXXXX or visit <u>www.xxxxxxxxxxxcom</u> and request document XXXXXXX